510(k) Summary

K040773

APR - 9 2004

- Pelvis BellyBoard PLUS
- SecureVac System
- SecureFoam System
- SecureFit Bar
- Extended Butterfly Armboard

1. Pelvis BellyBoard PLUS

Date Prepared: January 27, 2004

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Trade Name: Pelvis BellyBoard PLUS Patient Positioning System

Common Name: Belly Board Patient Immobilization System

Classification Name: Medical charged-particle radiation therapy system, accessory (per CFR section 892.5050)

Intended Use: The Pelvis BellyBoard PLUS from Bionix Development Corporation is designed to be used for the positioning and re-positioning of patients for receiving radiation therapy.

Claim of Substantial Equivalence:

This product is similar in design and function to existing patient positioning devices currently in use as accessories to radiation therapy systems.

One such device is the Advanced Belly board System manufactured and legally marketed by Med-Tec, Inc. of Orange City, Iowa. This device has been classified as a Class II device by the FDA, and has been granted marketing clearance and has been assigned the document control number K023293.

The Advanced Belly board System from Med-Tec consists of a thermoformed plastic shell with a foam core. The device has a generally rectangular contour, with specific areas for placement of head, abdominal, and leg cushions. The cushions are affixed to the thermoplastic shell with Velcro strips. Other important features of the device are simple mechanical interlocking systems for attaching the Advanced Belly board

System to the top of the radiation therapy couch, and for the attachment of contoured low-melt thermoplastic sheets that are used to further position and hold the patient.

The thermoplastic/foam composite structure of the board has a minimal attenuation factor. This is due primarily to the foam core of the composite, which being mostly air blocks little of the radiation. Standard dosimetry has been used to document this fact, and such results have been widely published in the medical literature. The thermoformed plastic skin provides strength and stiffness; in aggregate, such structures are ideal for producing devices that reproducibly position patients and yet do not interfere with the administration of the therapeutic radiation. Patient positioning devices with this type of composite structure are common in radiation therapy. They come in many varieties and are manufactured by several companies; examples include Med-Tec, Aktina, Arplay, and Bionix.

In practice, the Med-Tec Advanced Belly board System is secured to the therapy couch tabletop by a lock-down mechanism, or by the patient's own weight. The patient is positioned prone on the board with his head resting on a cushion at the head of the board. The patient's abdomen is positioned over the abdominal cushion such that the belly drops into the cutout region provided in the abdominal cushion. A mask of the patient's buttocks and upper thighs is made by stretching warm, pliable low-melt thermoplastic over the patient, and then securing that mask to the board using the interlocking mechanism (in this case, a plastic swivel clamping system) described earlier. As the low-melt thermoplastic cools, it becomes rigid, taking and holding the shape of the patient. In this fashion, the patient is positioned reproducibly on the board. Radiation therapy is then administered in the usual fashion. (Copies and marketing materials from the Med-Tec, Inc. catalog and website are appended to this document to substantiate and clarify the above claims as to design and use of the Med-Tec Advanced Belly board System.)

The Bionix Pelvis BellyBoard PLUS is substantially equivalent to the Med-Advanced Belly board System in design, construction, and function. The Pelvis BellyBoard PLUS is flat and has a similar, generally rounded rectangular-shaped contour, with areas specifically designed for the head, abdomen, and thighs. Specially designed cushions that fit in these areas of the Pelvis BellyBoard PLUS are used to position and support the patent. The head cushion has a contoured opening so that the patient may rest his/her head comfortably in the prone position during the treatment process. The abdominal cushion is also designed with an open, contoured cutout region. The patient is positioned over the abdominal cushion such that the belly drops into the cutout region during the radiation therapy session. Contoured thigh cushions are provided for patient comfort and support. The cushions are affixed to the thermoplastic shell of the Pelvis BellyBoard PLUS using Velcro strips in the usual fashion.

The Bionix Pelvis BellyBoard PLUS is manufactured according to the FDA Good Manufacturing Practice guidelines using standard methods and practices. The Pelvis BellyBoard PLUS is constructed in a manner similar to the Advanced Belly board System from Med-Tec, having a thermoformed thermoplastic Kydex® shell with an air core that is an accepted standard in radiation therapy. The thermoformed Kydex®

shell again provides stiffness and strength, while the air core allows for almost no attenuation of the radiation beam during the treatment process. The Pelvis BellyBoard PLUS also has simple mechanical interlocks that allow the board to be secured to the tabletop of the therapy couch. Other interlocks or clamps allow low-melt thermoplastic to be attached to the Pelvis BellyBoard PLUS during the patient positioning process. (Engineering drawings and perspective views, as well as digital images of the prototype device are appended to this document to substantiate the above claims as to design and structure of the Bionix Pelvis BellyBoard PLUS, as production models are not yet available.)

In clinical practice, the Pelvis BellyBoard PLUS again functions similarly to the Med-Tec Advanced Belly board System. The patient is generally positioned on the Pelvis BellyBoard PLUS in the prone position, with his head resting on a foam cushion for support. The patient is situated such that his abdomen drops into the contoured cutout region provided in the abdominal cushion. Warm low-melt thermoplastic in its pliable state is then draped over the patient's buttocks and thighs where it conforms to the patient's anatomy. It is then secured to the Pelvis BellyBoard PLUS using clamps or other simple mechanical interlocks. When it cools, the low-melt thermoplastic becomes rigid and retains the shape of the patient, allowing him to be positioned and re-positioned securely during the radiation therapy regimen.

An alternative method of use for the Bionix Pelvis BellyBoard PLUS is to use the device for positioning a patient in the supine position. This is sometimes done for alternative treatment protocols such as radiation therapy of the prostate. In practice, the patient is placed in the supine position on the Pelvis BellyBoard PLUS either using the standard foam cushions, or alternatively, replacing the standard cushions with a SecureVac or SecureFoam cushion custom molded to the patient's anatomy. These custom molded cushions provide the same air-equivalent radiolucency as the standard foam cushions, and key into ridges that are molded into the base of the Pelvis BellyBoard PLUS in order to provide a secure fit of the custom cushion to the board. Low-melt thermoplastic may be used as described above to contour to the patient's anatomy, allowing him to be positioned and re-positioned securely during the radiation therapy regimen. Again, radiation therapy is then administered in the usual fashion.

Based on the almost identical design and construction of the Bionix Pelvis BellyBoard PLUS to the Advanced Belly board System currently manufactured and sold by Med-Tec, Inc., it is reasonable to expect that the two devices will have similar properties as regards to stiffness, support strength, and minimal attenuation of the radiotherapy beam, and should function in a substantially equivalent fashion during the patient positioning and the radiation therapy process. Both the Pelvis BellyBoard PLUS and the Med-Tec Advanced Belly board System are intended for use in positioning and re-positioning patients during radiation therapy procedures, and both boards are employed in clinically identical fashions. Therefore, it is reasonable to conclude that the Pelvis BellyBoard PLUS manufactured by Bionix Development Corporation is substantially equivalent in all aspects to the Advanced Belly board System manufactured by Med-Tec, Inc.

Another such device is the AccuFix IMRT Quick-fix Carbon Fiber Pelvis System from WFR/Aquaplast Corp. The WFR/Aquaplast Corp. AccuFix IMRT Quick-fix Carbon Fiber Pelvis System is constructed of a composite material with a carbon fiber/epoxy skin and a foam core. The carbon fiber/epoxy/foam composite structure of the board provides strength and stiffness yet has a minimal attenuation factor. This is due primarily to the foam core of the composite, which being mostly air blocks little of the radiation. The AccuFix board can be indexed or repeatably mounted to most treatment tabletops. The Quick-fix pelvis system can be used with a wide variety of different shapes and sizes low-melt thermoplastic to assist patient positioning and repositioning.

In clinical practice the AccuFix board functions similarly to the Pelvis BellyBoard PLUS from Bionix Development Corp. The AccuFix board is positioned and secured to the treatment table couch by a lock-down mechanism or the patient's own weight. The patient is positioned on the board in the supine position, with his head resting on a cushion and his knees maintained in a flexed position by cushions that support his thighs. A mask of the patient's mid-region and upper thighs is made by stretching warm, pliable low-melt thermoplastic over the patient, and then securing that mask to the board using a plastic swivel clamping system as described earlier. As the low-melt thermoplastic cools, it becomes rigid, taking and holding the shape of the patient. In this fashion, the patient is positioned reproducibly on the board. Radiation therapy is then administered in the usual fashion. Like the Bionix Pelvis BellyBoard PLUS, the AccuFix board from WFR/Aquaplast demonstrates minimal attenuation of the radiation therapy beam.

Based on the similar design and intended use of the Bionix Pelvis BellyBoard PLUS to the AccuFix IMRT Quick-fix Carbon Fiber Pelvis System currently manufactured and sold by WFR/Aquaplast Corp., it is reasonable to expect that the two devices will have similar properties as regards to stiffness, support strength, and minimal attenuation of the radiotherapy beam, and should function in a substantially equivalent fashion during the patient positioning and the radiation therapy process. Both the Pelvis BellyBoard PLUS and the WFR/Aquaplast AccuFix System are intended for use in positioning and re-positioning patients during radiation therapy procedures, and both boards are employed in clinically identical fashions. Therefore, it is reasonable to conclude that the Pelvis BellyBoard PLUS manufactured by Bionix Development Corporation is substantially equivalent in all aspects to the AccuFix IMRT Quick-fix Carbon Fiber Pelvis System from WFR/Aquaplast Corp.

2. **SecureVac Immobilization System**

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Trade Name: SecureVac Immobilization System

Common Name: Vacuum Bag Immobilization System

Classification Name: Medical charged-particle radiation therapy system, accessory (per CFR section 892.5050)

Intended Use: The SecureVac Immobilization System from Bionix Development Corporation is designed to be used for the positioning and re-positioning of patients for receiving radiation therapy.

Claim of Substantial Equivalence:

This product is similar in design and function to existing patient positioning devices currently in use as accessories to radiation therapy systems.

One such device is the Vac-Lok System manufactured and legally marketed by Med-Tec, Inc. of Orange City, Iowa. This device has been classified as a Class II device by the FDA, and has been granted marketing clearance and has been assigned the document control number K935300.

Another such device is the Vac Fix System manufactured and legally marketed by S&S Par Scientific of Great Neck, New York. This device has been classified as a Class II device by the FDA, and has been granted marketing clearance and has been assigned the document control number K895697.

The Vac-Lok Immobilization System from Med-Tec consists of bags made from a nylon-reinforced blue urethane material that is filled with tiny polystyrene beads. The bags are sealed to be airtight, and are fitted with a closeable check valve. The bags have air-equivalent radiolucency owing to the polystyrene bead filler that is used and the relatively thin polyurethane film forming the skin of the bag. Standard dosimetry has been used to document this fact, and such results have been widely published in the medical literature.

In practice, the Vac-Lok bag is placed on a patient immobilization device, and the patient is positioned on top of the bead filled cushion. A vacuum pump is attached to

the bag's check valve, and the air is evacuated from the bag. As the air is removed, the bag compresses around the polystyrene beads forming a rigid structure that conforms to the anatomy of the patient. When completely evacuated of air, the vacuum pump is disconnected and the check valve is sealed, maintaining the evacuated, compressed condition of the bag. With each new treatment session, the evacuated bag is placed on the patient immobilization device. The patient then "settles-in" to the indentation in the compressed evacuated bag that now conforms to his anatomy. In this way, the patient may be reliably re-positioned each time for his/her radiation therapy session.

The Bionix SecureVac Immobilization System is substantially equivalent to the Med-Tec Vac-Lok Immobilization System in design, construction, and function. The SecureVac bags are constructed from strong, vinyl coated nylon material that is filled with small polystyrene spheres to immobilize the patient. Each bag is double sealed airtight and fitted with a self-closing valve for ease of use. It also features a pinch clamp system for more security. Once evacuated, the SecureVac cushion holds a rigid shape over the course of the radiation therapy treatment regimen.

In clinical practice, the SecureVac cushion is placed on an immobilization device such as the Bionix Pelvis BellyBoard PLUS, and the patient is then positioned on top of the SecureVac cushion. A vacuum pump is attached to the check valve on the SecureVac bag, and the air is evacuated from the bag. As the air is removed, the bag compresses around the polystyrene beads forming a rigid structure that conforms to the anatomy of the patient. When completely evacuated of air, the vacuum pump is disconnected, the check valve is sealed and the pinch clamp is closed maintaining the evacuated, compressed condition of the bag. As with the Med-Tec Vac-Lok bag, the SecureVac forms a rigid cushion with an indentation conforming to the anatomy of the patient. For each therapy session, the patient can easily relocate his/her position with certainty by slipping into the pre-formed depression in the SecureVac cushion, enhancing the accuracy of the radiation treatment.

The Bionix SecureVac Immobilization System is manufactured according to the FDA Good Manufacturing Practice guidelines using standard methods and practices. The SecureVac cushion is constructed in a manner similar to the Vac-Lok Immobilization System from Med-Tec, having a plastic nylon/vinyl film skin and filled with small polystyrene beads. The bag is sealed to be airtight, and an integral check valve is used to deflate and re-inflate the bag, and to maintain the bag in an evacuated state.

Bionix Development Corporation is also claiming substantial equivalence for its SecureVac Immobilization System to the legally marketed, Class II device, "Vac Fix System", manufactured and sold by S&S Par Scientific of Great Neck, New York. The S&S Par Scientific Vac Fix System consists of a bag made from a urethane film, and filled with polystyrene beads. The Vac Fix bag is fitted with a check valve, and is sealed to be airtight.

In practice, the S&S Par Scientific Vac Fix bag is placed on a patient immobilization device, and the patient is positioned on top of the bead filled cushion. A vacuum pump is attached to the bag's check valve, and the air is evacuated from the bag. As

the air is removed, the bag compresses around the polystyrene beads forming a rigid structure that conforms to the anatomy of the patient. When completely evacuated of air, the vacuum pump is disconnected and the check valve is sealed, maintaining the evacuated, compressed condition of the bag. With each new treatment session, the evacuated bag is placed on the patient immobilization device. The patient then "settles-in" to the indentation in the compressed evacuated bag that now conforms to his anatomy. In this way, the patient may be reliably re-positioned each time for his/her radiation therapy session.

In use, the SecureVac cushion functions similarly to the S&S Par Scientific Vac Fix System. The SecureVac is placed on an immobilization device such as the Bionix Pelvis BellyBoard PLUS, and the patient is then positioned on top of the SecureVac cushion. A vacuum pump is attached to the check valve on the SecureVac bag, and the air is evacuated from the bag. As the air is removed, the bag compresses around the polystyrene beads forming a rigid structure that conforms to the anatomy of the patient. When completely evacuated of air, the vacuum pump is disconnected, the check valve is sealed and the pinch clamp is closed maintaining the evacuated, compressed condition of the bag. As with the Med-Tec Vac-Lok bag, the SecureVac forms a rigid cushion with an indentation conforming to the anatomy of the patient. For each therapy session, the patient can easily relocate his/her position with certainty by slipping into the pre-formed depression in the SecureVac cushion, enhancing the accuracy of the radiation treatment.

The Bionix SecureVac bag is constructed in a manner similar to the S&S Par Scientific Vac Fix bag, and in accordance with the FDA Good Manufacturing Practice guidelines using standard methods and practices. Both the SecureVac cushion and the Vac Fix bag are made from a plastic film bag filled with polystyrene beads and sealed to be airtight. A check valve is bonded to the bag to maintain the bag in the evacuated or non-evacuated state.

Based on the almost identical design and construction of the Bionix SecureVac Immobilization System to the Vac-Lok Immobilization System currently manufactured and sold by Med-Tec, Inc., and to the Vac Fix System manufactured and sold by S&S Par Scientific, it is reasonable to expect that these devices will have similar properties and attenuation factors, and should function in a substantially equivalent fashion during the patient positioning and the radiation therapy process. The SecureVac Immobilization System, the Vac-Lok Immobilization System, and the Vac Fix System are all intended for use in positioning and re-positioning patients during radiation therapy procedures, and are employed in clinically identical fashions. Therefore, it is reasonable to conclude that the SecureVac Immobilization System manufactured by Bionix Development Corporation is substantially equivalent in all aspects to the Vac-Lok Immobilization System manufactured by Med-Tec, Inc., and the Vac Fix System manufactured and sold by S&S Par Scientific.

3. SecureFoam

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Trade Name: SecureFoam

Common Name: Two-Part Foaming Agent

Classification Name: Medical charged-particle radiation therapy system, accessory (per CFR section 892.5050)

Intended Use: The SecureFoam from Bionix Development Corporation is designed to be used for the positioning and re-positioning of patients for receiving radiation therapy.

Claim of Substantial Equivalence:

This product is similar in design and function to existing patient positioning devices currently in use as accessories to radiation therapy systems.

One such device is RediFoam manufactured and legally marketed by Med-Tec, Inc. of Orange City, Iowa. This device has been classified as a Class II device by the FDA, and has been granted marketing clearance and has been assigned the document control number K951808.

Another such device is Rapid-Foam manufactured and legally marketed by Soule, Inc. of Tampa, Florida. This device has been classified as a Class II device by the FDA, and has been granted marketing clearance and has been assigned the document control number K952457.

The Med-Tec RediFoam is a two-part foaming agent comprised of a part A (diisocyanate) and a part B (polyol). When reacted together, the polyol (part B) and diisocyanate (part A) combine to form a water-blown foaming system used for patient immobilization.

The Med-Tec RediFoam has a minimal attenuation factor. This is because the polyurethane foam that is produced by the reaction of the two components is mostly air-filled and is effectively air-equivalent, blocking little of the radiation. Standard dosimetry has been used to document this fact, and such results have been widely published in the medical literature.

In clinical practice, the two components are reacted together and then poured into a plastic bag. The bag containing the reacted components is placed over a patient immobilization device, and the patient is then placed into the desired position overtop the bag. The reacted components create a water-blown foaming system that expands the bag around the patient and readily cures to hardness, immobilizing the patient in the desired conformation. The hardened RediFoam conforms to the contour of the immobilization device as well as the anatomy of the patient. With each new treatment session, the rigid foam cushion is placed on the patient immobilization device. The patient then "settles-in" to the indentation in the rigid foam that now conforms to his anatomy. In this way, the patient may be reliably re-positioned each time for his/her radiation therapy session.

The Bionix SecureFoam is also a two-part foaming system comprised of Part B (polyol) and Part A (diisocyanate) components. The reaction of the polyol and diisocyanate components produces a water-blown polyurethane foam that hardens to rigidity as it cures. The polyurethane foam produced by this process is mostly air-filled, and thus has an air-equivalent radiolucency similar to that of the Med-Tec RediFoam.

In clinical practice, the Bionix SecureFoam is used in the same fashion as the Med-Tec RediFoam. The Part A and Part B components are reacted together and then poured into a plastic bag. The bag containing the reacted components is placed over a patient immobilization device such as the Bionix Pelvis BellyBoard PLUS (used for this purpose with the cushions), and the patient is then placed into the desired position overtop the bag. The reacted components create a water-blown foaming system that expands the bag around the patient and rapidly cures to hardness, immobilizing the patient in the desired conformation. The hardened SecureFoam conforms to the ridges and contours on the base of the Pelvis BellyBoard PLUS, as well as conforming to the anatomy of the patient. With each new treatment session, the rigid SecureFoam cushion can be fitted to the Pelvis BellyBoard PLUS in the same position. The patient then "settles-in" to the indentation in the rigid foam that now conforms to his anatomy. In this way, the patient may be reliably re-positioned each time for his/her radiation therapy session.

Bionix Development Corporation is also claiming substantial equivalence for its SecureFoam to the legally marketed, Class II device, "Rapid-Foam", manufactured and sold by Soule Co., Inc. of Tampa, Florida. Like the Med-Tec RediFoam and the Bionix SecureFoam, the Soule, Inc. Rapid-Foam is a two-part foaming agent comprised of a part A (diisocyanate) and a part B (polyol). When reacted together, the polyol (part B) and diisocyanate (part A) combine to form a water-blown rigid polyurethane foam that may be used for patient immobilization. The polyurethane foam produced by this process is mostly air-filled, and thus has an air-equivalent radiolucency similar to that of the Med-Tec RediFoam and the Bionix SecureFoam.

Again, in clinical use the Bionix SecureFoam and the Soule, Inc. Rapid-Foam are employed in similar fashion. The Part A and Part B components are reacted together and then poured into a plastic bag. The bag containing the reacted components is placed over a patient immobilization device and the patient is then placed into the

desired position overtop the bag. The reacted components create a water-blown foaming system that expands the bag around the patient and rapidly cures to hardness, immobilizing the patient in the desired conformation. The hardened Rapid-Foam forms a rigid cushion with an indentation conforming to the anatomy of the patient. The underside of the rigid foam conforms to contours of the patient immobilization device for accurate re-positioning on the device. For each therapy session, the patient can thus easily relocate his/her position with certainty by slipping into the pre-formed depression in the rigid Rapid-Foam cushion, ensuring the accuracy of the radiation treatment.

Based on the almost identical composition and mixing process of the Bionix SecureFoam to the RediFoam currently manufactured and sold by Med-Tec, Inc., and to the Rapid-Foam manufactured and sold by Soule, Inc. it is reasonable to expect that these devices will have similar properties and attenuation factors, and should function in a substantially equivalent fashion during the patient positioning and the radiation therapy process. The Bionix SecureFoam, the Med-Tec RediFoam, and the Soule, Inc. Rapid-Foam are all intended for use in positioning and re-positioning patients during radiation therapy procedures, and are employed in clinically identical fashions. Therefore, it is reasonable to conclude that the SecureFoam manufactured by Bionix Development Corporation is substantially equivalent in all aspects to the RediFoam manufactured by Med-Tec, Inc., and the Rapid-Foam manufactured and sold by Soule, Inc.

4. **SecureFit Bar**

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Trade Name: SecureFit Bar

Common Name: Indexing Bar

Classification Name: Medical charged-particle radiation therapy system, accessory (per CFR section 892.5050)

Intended Use: The SecureFit Bar from Bionix Development Corporation is designed to be used for the indexing of patient immobilization devices to a treatment couch top.

Claim of Substantial Equivalence:

This product is similar in design and function to existing patient positioning devices currently in use as accessories to radiation therapy systems.

One such device is the Exact Lok-Bar manufactured and legally marketed by Med-Tec, Inc. of Orange City, Iowa. This device has been classified as a Class II device by the FDA, and has been granted marketing clearance and has been assigned the document control number K973842.

The Med-Tec Exact Lok-Bar provides a means to position a patient immobilization device such as a belly board on a treatment couch top. The Exact Lok-Bar from Med-Tec is constructed of a rigid aluminum bar machined to the width of a treatment couch top, with engagement pins on its underside that fit into indentations on the side of the treatment couch top. One of the engagement pins is affixed to the bar with a cam-like pivot that, when turned, draws the cam inward and tightens the Exact Lok-Bar in the indentations to hold it securely to the treatment couch.

In typical use, the Exact Lok-Bar mates with a portion of the patient immobilization device that is not intended to be in the treatment field. Thus, in general there is no need for this device to be radiolucent, since it does not come between the patient and the radiation therapy beam.

The Exact Lok-Bar also has engagement pins on its surface that mate with corresponding holes on the patient immobilization device. In clinical practice,

radiation therapy treatment couch tops often have indentations along their edges that are numbered and used to index patient immobilization devices reproducibly between treatment sessions. In use, the Exact Lok-Bar is affixed to the treatment couch top in that manner described above, and tightened by rotating the cam-like pivot. Once securely fixed in the desired position, the patient immobilization device is placed over the Exact Lok-Bar, mating the corresponding holes on the immobilization device with the engagement pins on the Exact Lok-Bar. In this way, the patient immobilization device can be reproducibly indexed to the treatment couch top, assuring reliable re-positioning of the immobilization device between treatment sessions.

The Bionix SecureFit Bar also provides a ready means to position a patient immobilization device such as the Bionix Pelvis BellyBoard PLUS on a treatment couch top. The Bionix SecureFit Bar is comprised of either aluminum or a rigid carbon fiber/epoxy laminate material. In clinical practice, radiation therapy treatment couch tops often have indentations along their edges that are numbered and used to index patient immobilization devices reproducibly between treatment sessions. The SecureFit Bar has an engagement pin on one end and a cam-type pivot on its other end that allows it to lock into these indentations and securely hold the bar in position on the treatment couch top. Locator pins on the SecureFit Bar engage matching openings on the underside of the immobilization device, in this case the Bionix Pelvis BellyBoard PLUS, allowing the immobilization device to be reproducibly indexed to the treatment couch top.

Based on the almost identical design and construction of the Bionix SecureFit Bar to the Exact Lok-Bar currently manufactured and sold by Med-Tec, Inc., it is reasonable to expect that the two devices will have similar properties as regards to stiffness and strength, and should function in a substantially equivalent fashion during the patient positioning and the radiation therapy process. Both the Bionix SecureFit Bar and the Med-Tec Exact Lok-Bar are intended for use in reproducibly indexing patient immobilization devices such as a belly board to the treatment couch top, and both devices are employed in clinically identical fashions. Therefore, it is reasonable to conclude that the SecureFit Bar manufactured by Bionix Development Corporation is substantially equivalent in all aspects to the Exact Lok-Bar manufactured by Med-Tec, Inc.

5. Extended Butterfly Armboard

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Trade Name: Extended Butterfly Armboard

Common Name: Armboard

Classification Name: Medical charged-particle radiation therapy system, accessory (per CFR section 892.5050)

Intended Use: The Extended Butterfly Armboard from Bionix Development Corporation is designed to be used for the positioning and re-positioning of patients for receiving radiation therapy.

Claim of Substantial Equivalence:

This product is similar in design and function to existing patient positioning devices currently in use as accessories to radiation therapy systems.

Bionix Development Corporation is claiming substantial equivalence for its Extended Butterfly Armboard patient positioning device to the legally marketed, Class II device, "MT-200 Acrylic Breastboard", manufactured and sold by Med-Tec, Inc. of Orange City, Iowa. The document control number for this product's 510(k) submission is K935412.

The MT-200 Acrylic Breastboard from Med-Tec consists of two pieces of machined acrylic plastic hinged together to form the device. The upper piece serves as the patient support, and the lower piece forms the base of the device. Using the hinge joint, the upper piece may be angled in order to position the patient properly for a radiation therapy treatment session. A notched rod that rests in a pocket on the base and engages mating notches in the upper patient support maintains the patient support piece in the proper angled position. Threaded rods, which serve as handgrips allow the patient to reach up over her head to grasp the handgrips in such a fashion as to keep the arms elevated up and out of the treatment field. A cushion for support of the patient's lower back is added for comfort, and the device may be used with various headrests and cushions, also to improve patient comfort.

In practice, the Med-Tec MT-200 Acrylic Breastboard is either secured to the therapy couch tabletop by a lock-down mechanism, or simply rests on the treatment couch tabletop. The patient is positioned supine on the board with his head resting on a cushion or headrest. The patient then reaches up over his/her head and grasps handgrips. In doing so, the patient's upper arms are elevated up and out of the treatment field. The handgrips are adjustable; by recording the position of the handgrip and having the patient grasp the handgrip in the same manner and position each time, accurate re-positioning is ensured for each radiation therapy treatment session.

Depending on the treatment protocol, the patient support piece may be angled to elevate the patient, or the support rod may be omitted, and the patient treated flat in a true supine position. The choice of treatment position is determined by the therapy protocol chosen for the patient's disease.

After being correctly positioned on the MT-200 Acrylic Breastboard, radiation therapy is administered in the usual fashion. Copies and marketing materials from the Med-Tec, Inc. catalog and web site are appended to this document to substantiate and clarify the above claims as to design and use of the Med-Tec MT-200 Acrylic Breastboard.

The Bionix Extended Butterfly Armboard is substantially equivalent to the Med-Tec MT-200 Acrylic Breastboard in design, construction, and function. The Bionix Extended Butterfly Armboard is manufactured according to the FDA Good Manufacturing Practice guidelines using standard methods and practices. The Extended Butterfly Armboard is constructed of a single piece of polycarbonate plastic material that is machined and thermoformed to achieve the final product design. The Extended Butterfly Board has elevated thermoformed "wings" on either side to support the patient's upper arms and facilitate patient positioning and comfort. An adjustable T-Bar handgrip is attached to the board. The T-Bar handgrip adjusts in both the horizontal and vertical direction to facilitate patient positioning and re-positioning. Various headrests and cushions may be used to assist in patient positioning and improve patient comfort. The Bionix Extended Butterfly Armboard may be used alone or in conjunction with other patient positioning devices such as the Bionix Pelvis BellyBoard.

In clinical practice, the Extended Butterfly Armboard again functions similarly to the Med-Tec MT-200 Acrylic Breastboard when placed in the flat, true supine position. The Extended Butterfly Armboard may be used alone, or may be combined with other patient positioning devices for enhance utility. Mounting holes are provided in the base of the board for this purpose.

The patient is generally positioned on the Extended Butterfly Armboard in the supine position, with his head resting on a foam cushion for support. The patient then reaches up over his/her head and grasps the T-Bar handgrip. The T-Bar handgrip is adjustable; by ensuring that it is in the same position for each therapy session repeatable and reproducible positioning of the patient is ensured for each treatment session.

As the patient grasps the T-Bar handgrip, the "wings" on either side of the device support the patient's upper arms, providing support and comfort. Once the patient is accurately positioned or re-positioned, radiation therapy is administered in the usual fashion.

Based on the similar design, composition, and construction of the Bionix Extended Butterfly Armboard to the MT-200 Acrylic Breastboard currently manufactured and sold by Med-Tec, Inc., it is reasonable to expect that the two devices will have similar properties as regards to stiffness, support strength, and minimal attenuation of the radiotherapy beam, and should function in a substantially equivalent fashion during the patient positioning and the radiation therapy process. Both the Extended Butterfly Armboard and the Med-Tec MT-200 Acrylic Breastboard are intended for use in positioning and re-positioning patients during radiation therapy procedures, and when the Med-Tec MT-200 Acrylic Breastboard is positioned in the flat, true supine position, both boards are employed in clinically identical fashions. Therefore, it is reasonable to conclude that the Extended Butterfly Armboard manufactured by Bionix Development Corporation is substantially equivalent in all aspects to the MT-200 Acrylic Breastboard manufactured by Med-Tec, Inc.

Submitted by: _____

James Huttner M.D., Ph.D.
Vice President, New Product Development
Bionix Development Corporation

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 9 2004

Boinix Development Corporation
c/o Mr. Ned Devine
Entela, Inc.
3033 Madison Ave. SE
GRAND RAPIDS MI 49548

Re: K040773
Trade/Device Names:
Pelvis BellyBoard PLUS (Patient Positioning System)
SecureVac System
SecureFoam System
SecureFit Bar
Extended Butterfly Armboard
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: 90 IYE
Dated: March 26, 2004
Received: March 26, 2004

Dear Ms. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use For

- Pelvis BellyBoard PLUS
- SecureVac System
- SecureFoam System
- SecureFit Bar
- Extended Butterfly Armboard

1. Pelvis BellyBoard PLUS

Indications for Use

510(k) Number (if known):

Device Name: Bionix Pelvis BellyBoard PLUS

Indications for Use:

The Bionix Pelvis BellyBoard PLUS patient positioning system developed and manufactured by Bionix Development Corp., Toledo, Ohio, is intended to be used for the positioning and re-positioning of patients undergoing or receiving a course of external beam radiation therapy for the treatment of cancer and other diseases.

It is intended to be used by or under the direction of a licensed physician.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) ~~AND~~/OR Over-the-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lagerwall

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K042773

2. SecureVac System

Indications for Use

510(k) Number (if known):

Device Name: SecureVac

Indications for Use:

The Bionix SecureVac patient positioning system developed and manufactured by Bionix Development Corp., Toledo, Ohio, is intended to be used for the positioning and re-positioning of patients undergoing or receiving a course of external beam radiation therapy for the treatment of cancer and other diseases.

It is intended to be used by or under the direction of a licensed physician.

Prescription Use X (Part 21 CFR 801 Subpart D) ~~AND~~/OR Over-the-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

Emily A. Lyons

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K042773

3. SecureFoam System

Indications for Use

510(k) Number (if known):

Device Name: SecureFoam

Indications for Use:

The Bionix SecureFoam patient positioning system developed and manufactured by Bionix Development Corp., Toledo, Ohio, is intended to be used for the positioning and re-positioning of patients undergoing or receiving a course of external beam radiation therapy for the treatment of cancer and other diseases.

It is intended to be used by or under the direction of a licensed physician.

Prescription Use _X_ (Part 21 CFR 801 Subpart D) ~~AND~~/OR Over-the-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K062773

4. SecureFit Bar

Indications for Use

510(k) Number (if known):

Device Name: SecureFit Bar

Indications for Use:

The Bionix SecureFit Bar patient positioning device developed and manufactured by Bionix Development Corp., Toledo, Ohio, is intended to be used for the positioning and re-positioning of patients undergoing or receiving a course of external beam radiation therapy for the treatment of cancer and other diseases.

It is intended to be used by or under the direction of a licensed physician.

Prescription Use X (Part 21 CFR 801 Subpart D) ~~AND~~/OR Over-the-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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David A. Segmüller

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K040773

5. Extended Butterfly Armboard

Indications for Use

510(k) Number (if known):

Device Name: Extended Butterfly Armboard

Indications for Use:

The Bionix Extended Butterfly Armboard patient positioning device, developed and manufactured by Bionix Development Corp., Toledo, Ohio, is intended to be used for the positioning and re-positioning of patients undergoing or receiving a course of external beam radiation therapy for the treatment of cancer and other diseases.

It is intended to be used by or under the direction of a licensed physician.

Prescription Use __X__ ~~AND~~/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

David A. Segmon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K040773